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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,715	08/14/2001	Moncef Jendoubi	266/226	1686
34313	7590	08/04/2004	EXAMINER	
ORRICK, HERRINGTON & SUTCLIFFE, LLP			TRAN, MY CHAU T	
4 PARK PLAZA			ART UNIT	
SUITE 1600			PAPER NUMBER	
IRVINE, CA 92614-2558			1639	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,715	JENDOUBI, MONCEF	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 4/23/04 is acknowledged and entered. Claims 22 and 23 have been canceled. Claims 14, and 15-16 have been amended.
2. Claims 1-11 were canceled and Claims 14-23 were added by the amendment filed on 8/28/03.
3. Claims 12-13 were canceled and Claims 1 and 3 were amended by the amendment filed on 3/18/03.
4. Claims 14-21 are pending.

Withdrawn Objections and Rejections

5. The objection of claim 15 has been withdrawn in light of applicant's amendment of claim 15.
6. The rejections of claim 14 under 35 USC 112, second paragraph, regarding the correlation between the method step of providing at least two samples and the method step of containing the proteins in discrete areas has been withdrawn in light of applicant's amendments of claim 14.

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7. The rejections of claims 14, 15, and 21 under 35 USC 112, second paragraph, regarding the term “gene sequence” as being vague and indefinite has been withdrawn in light of applicant’s arguments, see pg. 4, lines 3-7, filed 4/23/04.

8. The rejections of claim 16 under 35 USC 112, second paragraph, regarding the phrase “comprised performed” as being vague and indefinite has been withdrawn in light of applicant’s amendments of claim 16.

9. The rejections of claim 21 under 35 USC 112, second paragraph, as being vague and indefinite with regard to claim 14 has been withdrawn in light of applicant’s arguments, see pg. 4, lines 11-16, filed 4/23/04.

10. The rejections of claim 23 under 35 USC 112, second paragraph, as being vague and indefinite with regard to claim 14 has been withdrawn in light of applicant’s cancellation of claims 23.

11. The rejections of claim 22 under 35 USC 112, second paragraph, as being incomplete for omitting essential steps has been withdrawn in light of applicant’s cancellation of claims 22.

12. The rejection of claims 14-15, and 17-21 under 35 USC 102(e) as being anticipated by Iris et al. (US Patent 6,403,309 B1; *filing date of 3/19/1999*) has been withdrawn in light of

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applicant's arguments, see pg. 5, lines 17-18, filed 4/23/04, wherein "*Iris et al. do not disclose a binding reaction to identify differential gene expression between two human samples.*"

Maintained Rejections

Claim Rejections - 35 USC § 112

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. Claim 14-23 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the "signaling" element for the detection of the antibody binding.

Response to Arguments

15. Since applicant did not present any argument(s) with regard to the rejection under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, the rejection is maintained.

Claim Rejections - 35 USC § 102

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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17. Claims 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bandaru (US Patent 6,462,187 B1; *filing date of 6/15/2000*).

Bandaru discloses a method of comparing the level of expressed polypeptide before and after treatment of the disorder (e.g. biological conditions) (col. 4, lines 9-13). The disorder includes cancerous condition (col. 10, lines 21-55). The method of detection comprised of detecting the binding interaction of the antibody specific to the expressed polypeptide (col. 37, lines 36-47). The method comprise of a two dimensional array having a plurality of addresses, each address of the plurality is positionally distinguishable from each other address of the plurality (col. 4, lines 35-45; col. 51, lines 37-67). Each address of the plurality can have a unique capture probe such as polypeptide, e.g. an antibody specific for the polypeptide. The plurality of addresses includes at least 10, 100, 500, 1,000, 5,000, 10,000, 50,000 addresses (col. 49, lines 14-16). The array can be use to assay gene expression in a tissue to ascertain tissue specificity of genes in the array (col. 49, lines 62-64) or to monitor expression of one or more genes in an array with respect to time for ascertaining differential expression patterns of one or more genes in normal or abnormal cells (col. 50, lines 32-45). Therefore the method of Bandaru anticipated the presently claimed method.

Response to Arguments

18. Applicant's arguments directed to the rejection under 35 USC 102(e) as being anticipated by Bandaru (US Patent 6,462,187 B1; *filing date of 6/15/2000*) for claims 14-21 were considered but they are not persuasive for the following reasons.

Applicant contends that the method of Bandaru does not anticipate the presently claimed method because 1) “*Bandaru does not disclose the step of containing human protein samples in*

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an array"; and 2) Bandaru does not refer to the analysis of gene expression information in a tissue sample is derived from the differential binding reactions at two discrete sites of the array. Thus the method of Bandaru does not anticipate the presently claimed method.

Applicant's arguments are not convincing since the method of Bandaru does anticipate the presently claimed method. The method of Bandaru does disclose the step of containing human protein samples in an array (col. 4, lines 9-13) and refer to the analysis of gene expression information in a tissue sample is derived from the differential binding reactions at two discrete sites of the array (col. 4, lines 35-40, and 43-45; col. 49, lines 62-64). Thus the method of Bandaru does anticipate the presently claimed method and this rejection is maintained.

19. Claims 14-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al. (US Patent 6,329,209 B1; *filing date 7/14/1999*).

Wagner et al. disclosed a method of comparing the protein expression of two cells or a population of cells that have been exposed to different conditions (col. 37, lines 19-67). The method comprises an array of protein-capture agents arranged in discrete, known regions of patches (col. 9, lines 66-67 to col. 10, lines 1-12). The array can have any number of a plurality of different protein-capture agents (col. 11, lines 1-11). For instance, an array comprise of about 10,000 patches would comprise of about 10,000 different protein-capture agents (col. 11, lines 28-33). Therefore, the number of different protein-capture agents on an array will vary depending on the application desired (col. 11, lines 12-13). The protein-capture agent would include biomolecule such as protein or polynucleotide (col. 4, lines 48-67) and would binds

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specifically to the antibody of interest (col. 12, lines 48-52). Therefore the method of Wagner et al. anticipates the presently claimed method.

Response to Arguments

20. Applicant's arguments directed to the rejection under 35 USC 102(e) as being anticipated by Wagner et al. (US Patent 6,329,209 B1; *filing date 7/14/1999*) for claims 14-21 were considered but they are not persuasive for the following reasons.

Applicant alleges that the method of Wagner et al. does not anticipate the presently claimed method because “*Wagner et al do not perform the method step of containing two tissue samples onto an array to obtain gene expression analysis.*” Thus the method of Wagner et al. does not anticipate the presently claimed method.

Applicant's arguments are not convincing since the method of Wagner et al. does anticipate the presently claimed method. The method of Wagner et al. does perform the method step of containing two tissue samples onto an array to obtain gene expression analysis because Wagner et al. define an array as an arrangement of entities in a pattern on a substrate (col. 6, lines 61-64) and the array have plurality of different protein-capture agents (col. 11, lines 1-4) (i.e. pluralities of different protein-capture agents are arranged in a pattern on a substrate). Wagner et al. discloses that protein-capture agents are proteins in a cell that specifically binds to another protein such as an antibody (col. 12, lines 50-52). Thus the method of Wagner et al. does perform the method step of containing two tissue samples onto an array to obtain gene expression analysis. Therefore, the method of Wagner et al. does anticipate the presently claimed method and this rejection is maintained.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

21. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

22. Claim 17 recites the limitation “*The method of claim 14 wherein the step of providing at least two samples that exhibit*” in line 1-2. There is insufficient antecedent basis for this limitation in the claim 14.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
8/1/2004


PADMASHRI PONNALURI
PRIMARY EXAMINER